UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,139	03/22/2006	Marc Purcell	31014/41879	3143

4743 7590 01/11/2008

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,139	PURCELL ET AL.	
	Examiner	Art Unit	
	Qiuwen Mi	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 22 March 2006 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/21/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Pending

Claims 1-11 are pending. Claims 1-11 are examined on the merits.

Claim Rejections –35 USC § 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A disease or disorder involving the formation of reactive oxygen species or inflammation cannot be prevented. There is no evidence that one would not ever get a disease or disorder involving the formation of reactive oxygen species or inflammation by consuming the claimed purified thylakoids. Unless Applicant can show on the record that a disease or disorder involving the formation of reactive oxygen species or inflammation would be completely prevented in every instance, Applicant is requested to cancel this the word "preventing".

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the invention only provides the description of treating TPA induced ear edema in rats with purified thylakoids, and no description regarding treating any disease or disorder involving the formation of reactive oxygen species is being disclosed in the specification. It is not clear exactly what diseases or disorders Applicant is referring to, and there is no description how those diseases would be treating by the claimed extract. Accordingly, in the absence of sufficient recitation of the compound with the corresponding structure and functional activity, the specification does not provide adequate written description of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed compound being claimed, and therefore conception is not achieved until reduction to practice has occurred,

regardless of the complexity or simplicity of the compound. Adequate written description requires more than a mere statement of the total amount of the plant material being used. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

Claims 1-4, and 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an extract from a medium, does not reasonably provide enablement for an isolated compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As evidenced by Waris et al (Jorunal of Carcinogenesis, 5:14, 1-8, 2006), reactive oxygen species is closely related with the development of cancer (see title) and various chronic conditions such as diabetes, atherosclerosis, viral infection and ischemia-reperfusion injury (page

3, right column, third paragraph). As mentioned above, the invention only provides the description the invention only provides the description of treating TPA induced ear edema in rats with purified thylakoids, and no description regarding treating any disease or disorder involving the formation of reactive oxygen species is being disclosed in the specification. As evidenced by Kamb (Kamb, Nature Reviews, 4: 161-165, 2005), cancer is among the most challenging of the therapeutic areas. The use of drugs that kill cells and which are consequently often toxic; and the rates of failure in expensive phase III trails that eclipse many other disease areas. The poor performance of most investigational cancer drugs implies that the standard preclinical disease models are faulty. It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to treating cancer or other reactive oxygen species related diseases, that Applicant is not enabled for the instant method claims. Considering this evidence, the skilled artisan, lacking information with regard to treating cancer, would necessarily need to perform tedious trial and error protocols without expectation of success in order to provide for the specific therapeutic uses as claimed.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to

scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Claim Rejections –35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, and 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility. The claims recite

preventing a disease or disorder involving the formation of reactive oxygen species or inflammation. The broadest reasonable interpretation of the term pathological condition merely requires that one subject gets sick. There is no evidence that a disease or disorder involving the formation of reactive oxygen species or inflammation would be prevented, therefore the utility would not be credible.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purcell et al (WO 01/49305) in view of Anderson et al (US 2005/0048148).

Purcell et al teach a process wherein the thylakoids are purified from cell components (page 21, 1st paragraph). The extract is intended to be used for the treatment or prevention of disease involving the generation of ROS, such as inflammatory disease or cancer. Purcell et al also teach that the isolated thylakoids constitutes a powerful antioxidant molecule have a scavenger activity towards ROS. This antioxidant is of a natural origin, and it should have no toxicity or adverse effect when employed in a reasonable concentration (page 28, 2nd paragraph). Purcell et al also claim a plant extract comprising substantially pure thylaloids in an integral state (claim 22) and in a dry state. Purcell et al further teach extracting thylakoids from 100 g of

spinach with buffers that are acceptable for human consumption and ascorbic further has the advantage of providing vitamin C to the consumer. The sorbitol has been added to preserve the integrity of the membrane.

Purcell et al do not teach the claimed dose of thylakoids, and do not explicitly teach taken thylakoids orally or as food supplement in pellet, granules or encapsulated powder with a carrier.

Anderson et al teach using thylakoid extract comprising purified functional phytosynthetic pigment for treating inflammation at 0.00005 to 500 mg per kg of subject's body weight (see Abstract, claims 1 and 7). Anderson et al also teach intra-peritoneal administration of thylakoid extract to the intestinal lumen of Male Wistar rats [0174, 0178].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the dose in Anderson et al to treat inflammation since Anderson et al teach that thylakoid extract has the ability to modulate the inflammatory process. Since the composition of Anderson et al yielded beneficial results in treating inflammation, one of ordinary skill in the art would have been motivated to make the modifications. Although Purcell et al do not explicitly teach taking thylakoids orally or as a food supplement, since Purcell et al teach that purified thylakoids being an antioxidant is of a natural origin, it should have no toxicity or adverse effect when employed in a reasonable concentration, and using extracting buffers that are acceptable for human consumption and ascorbic further has the advantage of providing vitamin C to the consumer; and Anderson et al also teach intra-peritoneal administration of thylakoid extract to the intestinal lumen of Male Wistar rats, it would be obvious for one of the

ordinary skill in the art to make the purified thylakoid into oral composition. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate carrier or a pharmaceutical form) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/
Patricia Leith
Primary Examiner
AU 1655